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| APPLICATION NO.   | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO.    | CONFIRMATION NO. |
|---|-------------|----------------------|------------------------|------------------|
| 10/546,132  | 12/12/2005  | Rulin Fan            | 2003946-0202 (SGEA/US) | 9915             |
| 24280   | 7590        | 02/20/2007           | EXAMINER               |                  |
| CHOATE, HALL & STEWART LLP<br>TWO INTERNATIONAL PLACE<br>BOSTON, MA 02110 |             |                      | ISSAC, ROY P           |                  |
|   |             | ART UNIT             | PAPER NUMBER           |                  |
|   |             |                      | 1623                   |                  |
| SHORTENED STATUTORY PERIOD OF RESPONSE                                    | MAIL DATE   | DELIVERY MODE        |                        |                  |
| 3 MONTHS  | 02/20/2007  | PAPER                |                        |                  |

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

|                              |                        |                     |  |
|------------------------------|------------------------|---------------------|--|
| <b>Office Action Summary</b> | <b>Application No.</b> | <b>Applicant(s)</b> |  |
|                              | 10/546,132             | FAN, RULIN          |  |
|                              | <b>Examiner</b>        | <b>Art Unit</b>     |  |
|                              | Roy P. Issac           | 1623                |  |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) Responsive to communication(s) filed on \_\_\_\_\_.
- 2a) This action is FINAL.                            2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) Claim(s) 120-139 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) Claim(s) \_\_\_\_\_ is/are allowed.
- 6) Claim(s) 120-139 is/are rejected.
- 7) Claim(s) \_\_\_\_\_ is/are objected to.
- 8) Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on \_\_\_\_\_ is/are: a) accepted or b) objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
  - a) All    b) Some \* c) None of:
    1. Certified copies of the priority documents have been received.
    2. Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
    3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

|  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)  | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)   | Paper No(s)/Mail Date. _____ .                                    |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)<br>Paper No(s)/Mail Date <u>8/19/2005</u> . | 5) <input type="checkbox"/> Notice of Informal Patent Application |
|  | 6) <input type="checkbox"/> Other: _____                          |

**DETAILED ACTION**

This application is a 371 of PCT/US04/04921 filed 02/18/2004 which claims benefit of 60/448,839 filed 02/20/2003.

The preliminary amendment filed 08/19/2005 in which claims 1-119 were cancelled is acknowledged. Claims 120-138 are currently pending and are examined on the merits herein.

***Claim Rejections - 35 USC § 102***

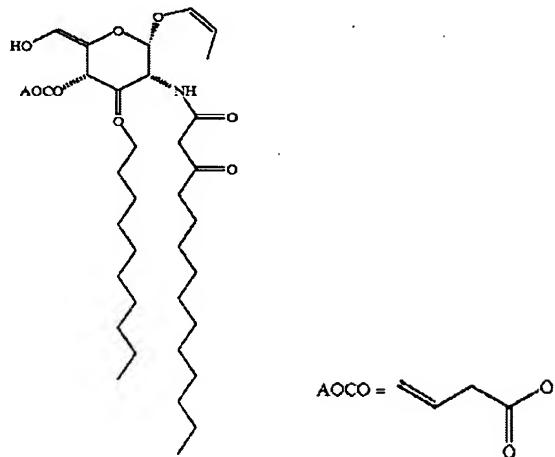
The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 129 is rejected under 35 U.S.C. 102(b) as being anticipated by Christ et. al. (U.S. Patent No. 6,184,366; PTO-892, Cited by the examiner).

Christ et. al. discloses the following compound (Column 45, lines 28-55);



Christ et. al. define AOCO as  $\text{CH}_2\text{CHCH}_2\text{C}(\text{O})\text{O}-$ . However this is considered a typographical error since protecting group of hydroxyls resulting from reaction of phosgene with allyl alcohol is recognized in the art to have a carbonate ester structure, i.e.  $\text{CH}_2\text{CHCH}_2\text{OC}(\text{O})\text{O}-$ . Christ et. al. discloses the reaction of phosgene with the alcohol followed by allyl alcohol. (Column 42, lines 45-56). As such, claim 129 is deemed anticipated by Christ et. al.

#### ***Claim Rejections - 35 USC § 103***

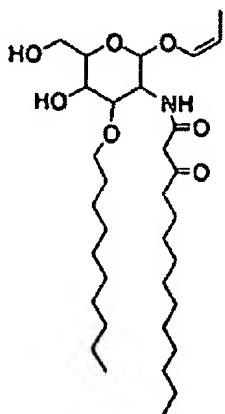
The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

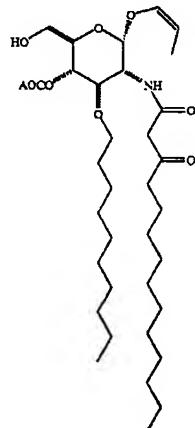
Claims 120-139 are rejected under 35 U.S.C. 103(a) as being unpatentable over Rossignol et. al. (U.S. Patent No. 6,184,366; PTO-892, Cited by the examiner).

Rossignol discloses the synthesis of liposaccharides with strong structural similarity to compounds of the instant application. The compounds of the instant application and compounds of the '366 patent are directed to the treatment of endotoxemia. (Abstract). The claimed compounds of the instant application are directed to the synthesis of liposaccharides used for the synthesis of lipodisaccharides. Rossignol discloses a synthetic route for the synthesis of liposaccharides. (Column 13-15). The synthetic strategy includes the use of cyclic acetal protecting groups for 6 and 4 position hydroxyl groups, allyl protecting group for hydroxyl and phosphate groups, as well as carbonate group for hydroxyl group. (Column 13-15). The trichloroacetonitrile protecting group, the TBS protecting group are also disclosed. (Column 19-20).

Compound of claim 125



Similar compound disclosed in the '366 patent

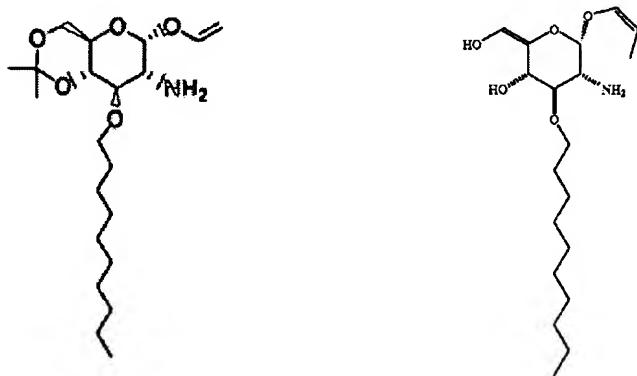


The only differences between these two compounds is the presence of the allyl carbonate protecting group in the '366 patent, which is removed in the final step of the

synthesis. (Column 53-54, Synthetic scheme), and that claim 125 is directed to a racemic compound. Compounds of claim 126, 128, 135, 136, 138 and 139 only differ from the illustrated compound of the '366 patent in the presence and absence of commonly used protecting groups for hydroxyl groups in carbohydrate chemistry. Compounds of claims 120-124, and 130-134 of the instant application differs from the above illustrated compound of the '366 patent in the presence of the cis-11-octadecanoyl side chain instead of the dioxotetradecyl side chain. The '366 patent further discloses the synthesis of lipodisaccharide with cis-11-octadecenoyl chloride. (Column 49-50).

Compounds of claim 137:

Compound of the '366 patent (Column 39):



The only difference between compound 137 and the above illustrated compound of the '366 patent is the presence of a cyclic acetal protecting group for the two hydroxyl groups the sugar moiety. Claim 127 is directed to the racemic form of the compound of claim 137. The '366 patent further discloses the use of cyclic acetal groups to protect

the same hydroxyl groups of the sugar moiety. (For example, synthetic scheme Column 13-14; Column 37-38).

The '366 patent does not expressly disclose the particular compounds of the instant application.

It would have been obvious to one of ordinary skill in the art to synthesize compounds of instant application because the '366 patent discloses compounds with the same core structure as the instant application and discloses the use of the same protecting groups in the synthesis of compounds of similar structure.

One of ordinary skill in the art would have been motivated to synthesize the particular compounds of the instant application because the '366 patent discloses compounds of similar structure for the treatment of endotoxemia.

As noted in MPEP 2144, "If such a species or subgenus is structurally similar to that claimed, its disclosure may motivate one of ordinary skill in the art to choose the claimed species or subgenus from the genus, based on the reasonable expectation that structurally similar species usually have similar properties. See, e.g., Dillon, 919 F.2d at 693, 696, 16 USPQ2d at 1901, 1904. See also Deuel, 51 F.3d at 1558, 34 USPQ2d at 1214. The utility of such properties will normally provide some motivation to make the claimed species or subgenus. Id. Dillon, 919 F.2d at 697, 16 USPQ2d at 1904-05 (and cases cited therein). If the claimed invention and the structurally similar prior art species share any useful property, that will generally be sufficient to motivate an artisan of ordinary skill to make the claimed species. In fact, similar properties may normally be presumed when compounds are very close in structure. Dillon, 919 F.2d at 693, 696, 16

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USPQ2d at 1901, 1904. See also *In re Grabiak*, 769 F.2d 729, 731, 226 USPQ 870, 871 (Fed. Cir. 1985) ("When chemical compounds have very close' structural similarities and similar utilities, without more a *prima facie* case may be made."). Thus, evidence of similar properties or evidence of any useful properties disclosed in the prior art that would be expected to be shared by the claimed invention weighs in favor of a conclusion that the claimed invention would have been obvious. *Dillon*, 919 F.2d at 697-98, 16 USPQ2d at 1905; *In re Wilder*, 563 F.2d 457, 461, 195 USPQ 426, 430 (CCPA 1977); *In re Linter*, 458 F.2d 1013, 1016, 173 USPQ 560, 562 (CCPA 1972).

Thus, one of ordinary skill in the art would have reasonably expected compounds with similar structure, with only difference in protecting groups would have resulted in substantially similar or better properties.

Thus, the claimed invention as a whole is clearly *prima facie* obvious over the combined teachings of the prior art.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Roy P. Issac whose telephone number is 571-272-2674. The examiner can normally be reached on 9:00-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Shaojia Anna Jiang can be reached on 571-272-0627. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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